

SCANNED

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
WESTERN DIVISION

VINCENT GILLESPIE
AND DOES 1-100,

Plaintiffs,

v.

ELI LILLY AND COMPANY
AND DOES 1-100,

Defendants.

3:03-cv-30196-MAP

DOCKETED

DOCKETED

BRIEF IN SUPPORT OF
DEFENDANT ELI LILLY AND COMPANY'S
MOTION FOR JUDGMENT ON THE PLEADINGS
AND MOTION TO DISMISS PLAINTIFF'S COMPLAINT

I. INTRODUCTION

This is a prescription drug product liability action in which plaintiff Vincent Gillespie claims that his father, Gregory Gillespie ("decedent"), committed suicide as a result of his ingestion of Prozac® (fluoxetine hydrochloride), a prescription antidepressant medication manufactured by Eli Lilly and Company ("Lilly"). This case was filed on April 25, 2003, but Lilly was not served with the Complaint until July 17, 2003. Plaintiff never served Lilly with a summons.

Plaintiff's Complaint contains five causes of action: "Count I – Wrongful Death;" "Count II – Conscious Pain and Suffering;" "Count III – Intentional Infliction of Emotional Distress;" "Count IV – Negligent Infliction of Emotional Distress;" and "Count V – Loss of Consortium." Because each count fails to state a claim under Massachusetts law, Lilly is entitled to judgment on the pleadings and plaintiff's Complaint should be dismissed.

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II. PLAINTIFF'S COMPLAINT SHOULD BE DISMISSED PURSUANT TO FED. R. CIV. P. 12(b)(4), 12(c) and 12(b)(6)

As demonstrated below, because plaintiff did not serve Lilly with a summons, process was insufficient in this case. In addition, each enumerated count in plaintiff's Complaint fails to state a claim upon which relief can be granted. For these reasons, plaintiff's Complaint should be dismissed.

A. Service of Process Was Improper Under MASS. R. CIV. P. 4(j), FED. R. CIV. P. 4(m) and LOCAL RULE 4.1(a)

This case was filed in Massachusetts state court. Massachusetts Rule of Civil Procedure 4(e), which governs service of process outside the Commonwealth, states that proper service is made under that rule by "delivering a copy of the summons and of the complaint." In addition, the Massachusetts Rules of Civil Procedure require plaintiff to promptly make proof of service in writing to the court. *See* MASS. R. CIV. P. 4(f). If service of the summons and complaint is not made within 90 days after filing, the action should be dismissed absent a showing of good cause by plaintiff as to why such service was not made. MASS. R. CIV. P. 4(j).¹

This case was filed on April 25, 2003, and plaintiff served Lilly with the complaint on July 14, 2003. Plaintiff did not serve Lilly with a summons. Indeed, the state court file does not contain a summons as it would had one been issued and returned as required by the Massachusetts Rules of Civil Procedure. Certified copy of Commonwealth of Massachusetts Superior Court Action No. 2003-083² attached as **Exhibit A**.

¹ FED. R. CIV. P. 4(m) similarly provides that if service of the summons and complaint is not made within 120 days after the complaint was filed, the action should be dismissed absent a showing of good cause by plaintiff as to why such service was not made. LOCAL RULE 4.1(a) further provides that: "Any summons not returned with proof that it was served within one hundred twenty (120) days of filing of the complaint is deemed to be unserved for the purpose of FED. R. CIV. P. 4(m)."

² Docket entry No. 5 in this case.

Lilly filed its answer in this case on August 12, 2003. Lilly's twenty-first affirmative defense states that "plaintiff's claims are barred because plaintiff's service of process upon Lilly was insufficient, in that, *inter alia*, plaintiff failed to serve a summons with the Complaint as required by MASS. R. CIV. P. 4(a) and FED. R. CIV. P. 4(c)(1)." Despite receiving this notice of insufficient service of process more than eight weeks ago, plaintiff has done nothing to rectify this defective service.

Plaintiff's failure to obtain and serve Lilly with a summons within 120 days after this case was filed constitutes insufficient process under both Massachusetts and Federal Rules of Civil Procedure. Despite notice of defective process from Lilly, plaintiff failed to move to enlarge the time for service of the summons or otherwise show good cause for his failure to obtain and serve a summons in this case. Pursuant to FED. R. CIV. P. 12(b)(4) and 4(m), LOCAL RULE 4.1(a) and Massachusetts Rule of Civil Procedure 4(j), plaintiff's case should be dismissed.

B. Plaintiff's Complaint Fails to State a Claim Upon Which Relief Can Be Granted

FED. R. CIV. P. 12(h)(2) provides that, after the close of the pleadings, the defense of failure to state a claim upon which relief can be granted may be raised by a FED. R. CIV. P. 12(c) motion for judgment on the pleadings. *Massachusetts Candy & Tobacco Distributors, Inc.*, 852 F. Supp. 63, 67 (D. Mass. 1994). When a FED. R. CIV. P. 12(c) motion raises a 12(b)(6) defense, the motion should be evaluated under the standard applicable to a 12(b)(6) motion. *Id.* (citing *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 11 (6th Cir. 1987)). A FED. R. CIV. P. 12(c) motion based upon failure to state a claim may be granted if it appears, according the facts alleged, plaintiff cannot recover under any viable theory of liability. *See Canty v. Old Rochester Regional School Dist.*, 54 F.Supp.2d 66, 68 (D. Mass. 1999). Because

plaintiff's Complaint fails to state a claim under any viable theory of liability,³ Lilly is entitled to judgment as a matter of law.

1. Lilly is Entitled to Judgment as a Matter of Law on "Count I – Wrongful Death"

On state law claims, such as the wrongful death claim set forth in Count I of plaintiff's Complaint, a plaintiff's capacity to sue is determined by Massachusetts law. *Comstock v. Pfizer Retirement Annuity Plan*, 524 F. Supp. 999, 1001-02 (D. Mass. 1981) ("On state law claims, capacity is determined by state law."); FED. R. CIV. P. 17(b) (capacity to sue or be sued is determined by the law of the state in which the district court is located). Under Massachusetts law, only the executor or administrator of the decedent's estate may bring a wrongful death and survival action. MASS. GEN. LAWS ANN. ch. 229, §§ 2, 6; *Hallett v. Town of Wrentham*, 398 Mass. 550, 555-56, 499 N.E.2d 1189, 1192-93 (1986); *MacDonald v. Moore*, 358 Mass. 801, 263 N.E.2d 464 (1970).

Plaintiff does not claim to be the executor or the administrator of the decedent's estate. Rather, plaintiff merely pleads that he is a "beneficiary and a legatee of the Estate of Gregory Gillespie" See Exhibit B at ¶¶ 1, 2, 10, 14⁴. Accordingly, Count I of plaintiff's Complaint fails to state a claim upon which relief can be granted and should, therefore, be dismissed. See FED. R. CIV. P. 12(b)(6); see also *Carroll v. Protection Maritime Ins. Co., Ltd.*, 377 F. Supp. 1294, 1296 (D. Mass. 1974) ("A motion to dismiss for failure to state a claim upon

³ While plaintiff does not specifically allege that Massachusetts law applies to this case, he seeks recovery under specific chapters of Massachusetts General Law. See, e.g., Count I, paragraph 13 ("[t]his count is for wrongful death pursuant to M.G.L. c. 229 § 2."). Plaintiff's Complaint attached as **Exhibit B**.

⁴ While not necessary to the resolution of this motion, Lilly notes that plaintiff *cannot* truthfully claim to be the executor or administrator of his father's estate. The decedent's wife, Peggy Gillespie, was appointed executrix of the decedent's estate on July 13, 2000. Decree appointing Mrs. Gillespie executrix of decedent's estate attached as **Exhibit C**.

which relief can be granted can properly be used to attack a plaintiff's capacity to sue"), *aff'd in part and rev'd in part on other grounds*, 512 F.2d 4 (1st Cir. 1975).

2. Lilly is Entitled to Judgment as a Matter of Law on "Count II – Conscious Pain and Suffering"

While this count is entitled "Conscious Pain and Suffering," it appears to be a survival action for damages allegedly sustained by the decedent following his ingestion of Prozac®, but prior to his death. *See* Exhibit B at ¶ 16 ("[t]his count is for Conscious Pain and Suffering pursuant to M.G.L. c. 229 §6"). The referenced statute provides that damages for conscious suffering resulting from the same injury that caused decedent's death are recoverable in a wrongful death action brought under MASS. GEN. LAWS ANN. ch. 229, §§ 2.

Like wrongful death actions, survival actions may only be brought by the executor of decedent's estate. *MacDonald*, 358 Mass. 801, 263 N.E.2d 464 (*citing* MASS. GEN. LAWS ANN. ch. 229, §§ 2 and 6) ("No action, of course, can be maintained for death or conscious suffering unless it is brought by the decedent's executor or administrator.") Because plaintiff did not, and cannot, claim that he is the executor or administrator of decedent's estate, the survival action set forth in Count II of plaintiff's Complaint fails to state a claim upon which relief can be granted and should be dismissed.⁵ *See* FED. R. CIV. P. 12(b)(6); *Carroll*, 377 F. Supp. at 1296.

3. Lilly is Entitled to Judgment as a Matter of Law on "Count III – Intentional Infliction of Emotional Distress"

Under Massachusetts law, plaintiff must plead and prove four specific elements to prevail on a claim for intentional infliction of emotional distress: (1) the defendant intended to inflict emotional distress or knew or should have known that emotional distress was the likely

⁵ Count II also alleges that Lilly is "strictly responsible to the plaintiff pursuant to M.G.L. c. 138 § 14." MASS. GEN. LAWS ANN. ch. 138, § 14, however, addresses the grant of special licenses (for the sale of alcoholic beverages) to managers of indoor and outdoor activities and has nothing to do with the allegations set forth in plaintiff's Complaint.

result of his conduct; (2) the defendant's conduct was extreme and outrageous, beyond all possible bounds of decency and utterly intolerable in a civilized society; (3) the defendant's actions were the cause of plaintiff's distress; and (4) plaintiff's emotional distress was so severe that no reasonable man could be expected to endure it. *Agis v. Howard Johnson Co.*, 371 Mass. 140, 144-45, 355 N.E.2d 315, 318-19 (1976)(citations omitted). Given the "ephemeral nature" of emotional distress claims, courts have narrowly construed intentional infliction of emotional distress claims. *Heinrich v. Sweet*, 49 F.Supp.2d 27, 39 (D. Mass. 1999).⁶ Under Massachusetts law, claims for intentional infliction of emotional distress are narrowed by requiring plaintiff to prove "substantially contemporaneous knowledge of the outrageous conduct" *Id.* (citing *Nancy P. v. D'Amato*, 401 Mass. 516, 522, 517 N.E.2d 824, 828 (1988)). Because plaintiff did not plead and cannot prove "substantially contemporaneous knowledge of the outrageous conduct," Lilly is entitled to judgment as a matter of law on plaintiff's intentional infliction of emotional distress claim.

a. Applicable Standard of Liability

In *Payton v. Abbott Labs*, 386 Mass. 540, 437 N.E.2d 171 (1982), the Massachusetts Supreme Judicial Court ("SJC") rejected the application of strict liability to product liability claims involving prescription drugs. Recognizing the distinction between prescription drugs and other products better suited to strict liability analysis, the Court stated:

Public policy favors the development and marketing of new and more efficacious drugs. The Restatement (Second) of Torts recognizes this policy by rejecting strict liability in favor of negligence for drug related injuries. Restatement (Second) of Torts § 402A, comment k (1965). . . . Imposition of such broad liability [beyond that delineated by negligence principles] could have a

⁶ See also *Dusoe v. Mobil Oil Corp.*, 167 F.Supp.2d 155, 165 (D. Mass. 2001)("[t]he standard for making a claim of intentional infliction of emotional distress is very high")(citing *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 195 (1st Cir. 1996)).

deleterious effect on the development and marketing of new drugs, . . .

Id. at 573-74. The SJC thus recognized that prescription drugs are not treated like other products under the law, *e.g.*, a stepladder or a lawnmower, and that Massachusetts public policy dictates that prescription drugs be exempted from strict liability and evaluated under principles of negligence. Both the SJC and federal courts applying Massachusetts law since *Payton* have confirmed the rule set forth in *Payton*. See *Garside v. Osco Drug, Inc.*, 976 F.2d 77 (1st Cir. 1992) (applying Massachusetts law); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, *cert. denied*, 474 U.S. 920 (1985); *Sanderson v. Upjohn Co.*, 578 F. Supp. 338 (D. Mass. 1984).

b. The Conduct at Issue

Plaintiff fails to identify Lilly's allegedly "outrageous conduct" at issue in this case. However, because plaintiff claims that the decedent's ingestion of Prozac® caused the decedent to kill himself, Lilly's only legally cognizable conduct that could be at issue is an alleged failure to warn prescribing physicians⁷ of risks purportedly associated with the use of its product. Because plaintiff did not plead and cannot prove his own substantially contemporaneous knowledge of Lilly's alleged failure to warn, or that such alleged failure "was 'extreme and outrageous,' was 'beyond all possible bounds of decency' and was 'utterly intolerable in a civilized community,'" plaintiff's intentional infliction of emotional distress claim must fail as a matter of law.

⁷ In product liability cases involving prescription drugs (other than oral contraceptives), a pharmaceutical manufacturer has a duty to warn the physician (*i.e.*, "learned intermediary") rather than the patient. See *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992).

c. No Duty to Third Parties

The majority of intentional infliction of emotional distress claims seek recovery for emotional distress suffered by the person against whom the extreme and outrageous conduct was directed. *Nancy P.*, 401 Mass. at 520, 517 N.E.2d at 827; *Dusoe v. Mobil Oil Corp.*, 167 F.Supp.2d 155, 166 (D. Mass. 2001)(denying recovery in part because defendant's allegedly outrageous conduct was not directed at plaintiffs). The Supreme Judicial Court of Massachusetts in fact noted that "[t]he prevailing view among courts which have considered the question is that an absent family member may not recover for severe emotional distress caused by extreme and outrageous conduct directed at another family member." *Nancy P.*, 401 Mass. at 521, 517 N.E.2d at 827. Without deciding whether it would allow recovery to absent family members, the SJC concluded that it would require substantially contemporaneous knowledge of the conduct and a severe emotional response to that conduct. *Id.* at 522, 517 N.E. 2d at 828.

d. Substantially Contemporaneous Knowledge

Plaintiff has not plead and cannot prove that he learned of Lilly's alleged failure to warn the decedent's prescribing physician of side effects allegedly associated with the ingestion at or near the time the decedent first took Prozac®. Because plaintiff did not learn of Lilly's alleged failure to warn at a time substantially contemporaneous with the occurrence of Lilly's alleged act or omission, plaintiff's intentional infliction of emotional distress claim must fail as a matter of law.

e. Lilly's Allegedly Outrageous Conduct

Prozac® is a prescription medication indicated for the treatment of depression and other mental illnesses. It was first approved for sale in the United States in 1987 and has been on the market in the United States since early 1988. Prozac® is approved for sale in more than 100 countries around the world.

Like all prescription medications, Prozac® can only be sold in the United States when accompanied by FDA-approved product labeling. Under federal law, the FDA can approve the marketing of a prescription drug only if it determines that a New Drug Application (“NDA”) includes “adequate tests by all methods reasonably applicable showing the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling.” 21 U.S.C. §§ 355(d)(1) and (d)(2). Under federal regulations, the FDA can approve labeling only if it believes the product labeling is: (1) supported by essential scientific information, (2) informative and accurate; and (3) supported by adequate and substantial evidence of safety and efficacy. 21 C.F.R. §§ 201.56(a)-(c). Prescription drug labeling must contain specific information concerning indications and usage, contraindications, warnings, precautions, adverse reactions and many other topics. 21 C.F.R. §§ 201.56; 201.57. FDA-approval of Lilly’s product labeling, as described above, compels the conclusion that Lilly’s conduct was not, as a matter of law, “extreme and outrageous,” “beyond all bounds of decency” and “utterly intolerable in a civilized community.”

In *Fisher v. American Red Cross Blood Services*, 139 Ohio App.3d 658, 745 N.E.2d 462 (2000), plaintiffs sued the American Red Cross (“Red Cross”) for intentional infliction of emotional distress.⁸ The conduct giving rise to those claims was the reporting of erroneous results from a Red Cross blood test.

When plaintiff donated blood at Red Cross, Red Cross routinely tested plaintiff’s blood for a number of diseases that could be harmful to the recipient of his blood. The results of Red Cross’ testing erroneously indicated that the plaintiff had syphilis. Pursuant to FDA

⁸ The elements of an intentional infliction of emotional distress claim under Ohio law are identical to those under Massachusetts law. *Compare Retterer v. Whirlpool Corp.*, 111 Ohio App.3d 847, 677 N.E.2d 417 (1996) with *Agis v. Howard Johnson Co.*, 371 Mass. 140, 355 N.E.2d 315 (1976).

regulations, Red Cross notified plaintiff of its blood testing results. *Id.* at 660, 745 N.E.2d at 463. Subsequent testing at area health care agencies revealed that plaintiff did not have syphilis. *Id.*

Plaintiffs sued Red Cross, alleging that the reporting of erroneous results of the plaintiff husband's blood test caused them to suffer severe emotional distress. *Id.* The trial court granted Red Cross' motion for summary judgment on plaintiffs' claim and plaintiffs appealed. The appellate court confirmed, holding that Red Cross' behavior was not extreme and outrageous conduct because it was "simply following the regulations, dictated by the FDA, which require positive tests to be reported to the donor." *Id.* at 662, 745 N.E.2d at 465.

The same result is warranted here. Lilly's product labeling which contains warning, precautions, adverse reactions, post-marketing events and other information concerning Prozac® is approved for use by the United States Food and Drug Administration. This fact alone prevents Lilly's warnings from being characterized as "extreme and outrageous," "beyond all bounds of decency" and "utterly intolerable in a civilized community" and entitle Lilly to judgment as a matter of law.

4. Lilly is Entitled to Judgment as a Matter of Law on "Count IV – Negligent Infliction of Emotional Distress"

The elements of an action for negligent infliction of emotional distress are "(1) negligence; (2) emotional distress; (3) causation; (4) physical harm manifested by objective symptomatology, and (5) that a reasonable person would have suffered emotional distress under the circumstances of the case." *Payton v. Abbott Labs*, 386 Mass. 540, 557, 437 N.E.2d 171, 181 (1982). Where a defendant's conduct is merely negligent, plaintiff cannot recover for a "purely mental disturbance." *Id.* at 552-53; 437 N.E.2d at 179. "[W]hen recovery is sought for

negligent, rather than intentional or reckless, infliction of emotional distress, evidence must be introduced that plaintiff has suffered physical harm.” *Id.* at 555, 437 N.E.2d at 180.

Plaintiff did not allege physical harm manifested by objective symptomatology in his negligent infliction of emotional distress claim. *See* Complaint at ¶¶ 24-26. For this reason, Count IV fails to state a claim upon which relief can be granted, and Lilly is entitled to judgment on the pleadings.

There are additional limitations to a cause of action for negligent infliction of emotional distress when, as here, the claim is based upon injury to a third person. *See Hannan v. Town of Yarmouth*, 1995 WL 1146852 at *3 (Mass. Super. Ct. 1995). The emotional distress for which plaintiff seeks to recover must be a result of the allegedly negligent act, as distinguished from the grief caused by the death of a loved one. *Id.* (citing *Miles v. Tabor*, 387 Mass. 783, 789, 443 N.E.2d 1302, 1305-06 (1982)); *see also Cohen v. McDonnell Douglas Corp.*, 389 Mass. 327, 342, 451 N.E.2d 581, 590 (1983). Under Massachusetts law, a plaintiff fails to state a cause of action for negligent infliction of emotional distress when he learns of his decedent’s death hours after the event. *Id.* (citing *Cohen v. McDonnell Douglas Corp.*, 389 Mass. 327, 341-42, 451 N.E.2d 581, 589 (1983) (plaintiff learned of her son’s death by telephone seven hours after he died and did not see the scene of the accident or her son’s injuries); *Stockdale v. Bird & Sons, Inc.*, 399 Mass. 249, 251-52, 503 N.E.2d 951, 953-54 (1987) (plaintiff learned of her son’s death four hours after he died and saw his body the next day at the funeral home)).

Plaintiff in this case pleads “sorrow, worry, great stress, anguish and depression.” as a result of his father’s death. *See* Exhibit B at Count IV. He does not claim that he was at his father’s house at the time his father died, or that the “sorrow, worry, great stress, anguish and

depression” he experienced was the result of the Lilly’s allegedly negligent act⁹, as distinguished from the grief caused by the death of his father. For these reasons, Lilly is entitled to judgment as a matter of law on plaintiff’s negligent failure to warn claim.

5. Lilly is Entitled to Judgment as a Matter of Law on “Count V – Loss of Consortium”

There is no product liability or tort cause of action for loss of consortium under Massachusetts law. Because no such action exists, plaintiff has not, and cannot state a claim of “loss of consortium” and Count V should therefore be dismissed.

Loss of consortium *is* an element of damages recoverable under MASS. GEN. LAWS ANN. ch. 229, §§ 2. Plaintiff in a wrongful death case may not maintain a separate action for loss of consortium. *Hallett*, 398 Mass. At 556, 499 N.E.2d at 1193 (“We conclude that the wrongful death act, G.L. c. 229, § 2, provides the exclusive action for the recovery of damages it encompasses by the designated beneficiaries. The plaintiffs may not maintain a separate action for loss of consortium.”); *see also Stockdale*, 399 Mass. at 252-53, 503 N.E.2d at 955. Because plaintiff failed to state a claim for wrongful death under Massachusetts law, *see* § II(A)(1), *supra*, and because plaintiff may not maintain a separate action for loss of consortium, Lilly is entitled to judgment as a matter of law on Count V.

III. CONCLUSION

Plaintiff’s failure to serve Lilly with a summons and file proof of such service with the Court constitutes insufficient service of process which warrants dismissal of this case. In addition, based upon the facts alleged in his Complaint, plaintiff cannot recover under any

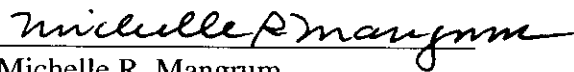
⁹ Again, although it is not stated, Lilly presumes its allegedly negligent act was its purported failure to warn the decedent’s prescribing physician of medical events allegedly associated with the ingestion of Prozac®.

viable theory of liability. Because plaintiff's Complaint fails to state a claim upon which relief can be granted, Lilly is entitled to judgment as a matter of law.

WHEREFORE, defendant Eli Lilly and Company respectfully requests that this enter judgment in its favor and against plaintiff, dismiss plaintiff's claims, with prejudice, and grant such other relief as the Court may deem just and proper.

Respectfully submitted,

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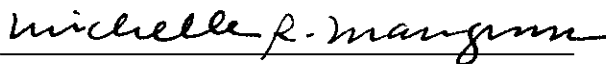
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Dated: October 20, 2003

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of October, 2003, a true and correct copy of this Brief in Support of Defendant Eli Lilly and Company's Motion for Judgment on the Pleadings and Motion to Dismiss Plaintiff's Complaint was mailed via first class U.S. Mail, postage prepaid thereon, to the following *pro se* plaintiff:

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